

AMENDED IN ASSEMBLY MARCH 29, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL

No. 595

Introduced by Assembly Member Negrete McLeod

February 17, 2005

An act to amend ~~Sections 4037 and~~ Section 4051 of, to add Section 4019.5 to, to repeal Section 4033 of, and to repeal and add Section 4123 of, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 595, as amended, Negrete McLeod. Pharmacy: compounding of prescription drugs.

~~The~~

Existing law, the Pharmacy Law, provides for the licensing and regulation by the California State Board of Pharmacy of pharmacists, pharmacies, and associated persons by the California State Board of Pharmacy. A other related practices and makes a violation of the that law is a crime. The Pharmacy Law defines various terms for its purposes, including "manufacturer".

This bill would delete the definition of manufacturer. The bill would define compounding of a prescription drug for the purposes of that law the Pharmacy Law and would make other related changes in that regard. Because this the bill would revise the definition of a crime specify requirements for compounded drug products under the Pharmacy Law, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 4019.5 is added to the Business and
2 Professions Code, to read:

3 4019.5. (a) “Compounding” means any of the following
4 activities occurring in a pharmacy pursuant to a prescription:

5 (1) Altering the dosage form, flavor, or delivery system of a
6 drug.

7 (2) Altering the strength of a drug.

8 (3) Combining components or active ingredients.

9 (4) Preparing a drug product from bulk chemicals.

10 (b) “Compounding” shall not include the reconstitution of a
11 drug pursuant to the manufacturer’s direction for oral, rectal, or
12 topical administration.

13 SEC. 2. Section 4033 of the Business and Professions Code is
14 repealed.

15 ~~SEC. 3. Section 4037 of the Business and Professions Code is~~
16 ~~amended to read:~~

17 ~~4037. (a) “Pharmacy” means an area, place, or premises~~
18 ~~licensed by the board in which the profession of pharmacy is~~
19 ~~practiced and where dangerous drugs and dangerous devices are~~
20 ~~stored. “Pharmacy” includes, but is not limited to, any area,~~
21 ~~place, or premises licensed by the board wherein controlled~~
22 ~~substances, dangerous drugs, or dangerous devices are stored,~~
23 ~~possessed, prepared, derived, compounded, repackaged,~~
24 ~~furnished, sold, or dispensed at retail.~~

25 ~~(b) “Pharmacy” shall not include any area in a facility licensed~~
26 ~~by the State Department of Health Services where floor supplies,~~
27 ~~ward supplies, operating room supplies, or emergency room~~
28 ~~supplies of dangerous drugs or dangerous devices are stored or~~
29 ~~possessed solely for treatment of patients registered for treatment~~
30 ~~in the facility or for treatment of patients receiving emergency~~
31 ~~care in the facility.~~

~~SEC. 4.~~

SEC. 3. Section 4051 of the Business and Professions Code is amended to read:

4051. (a) Except as otherwise provided in this chapter, it is unlawful for any person to compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052, and otherwise provide clinical advice or information or patient consultation if all of the following conditions are met:

(1) The clinical advice or information or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

~~SEC. 5.~~

SEC. 4. Section 4123 of the Business and Professions Code is repealed.

~~SEC. 6.~~

SEC. 5. Section 4123 is added to the Business and Professions Code, to read:

4123. (a) A compounded drug product shall only be dispensed or furnished to a patient pursuant to a prescription meeting the requirements of Section 4040.

(b) A compounded drug product shall only be dispensed or furnished to a patient where the prescription has been generated solely within an established professional relationship between the prescriber, patient, and dispensing pharmacy.

(c) A pharmacy may conduct anticipatory compounding of a drug product in limited quantity, as defined by regulation of the board, before receipt of a prescription order for that drug product, where the quantity of each drug product compounded in anticipation of receipt of prescription orders is based on a documented history of receipt of prescription orders generated solely within an established professional relationship between prescribers, patients of the pharmacy, and the pharmacy.

1 (d) A pharmacy may contract with another pharmacy to
2 compound drug products on behalf of its patients.

3 (e) A pharmacy may only base its anticipatory compounding
4 on a documented history of prescription orders received for its
5 own patients or customers, and not those patients or customers of
6 pharmacies with which it has a contractual relationship.

7 (f) Notwithstanding any other provision of this chapter, a
8 pharmacist may do both of the following:

9 (1) Compound a drug product pursuant to a prescription, for
10 delivery to another pharmacy pursuant to a contract for the
11 purpose of dispensing or furnishing the drug product to the
12 patient named in the prescription, provided that the drug is not
13 compounded prior to the receipt of the prescription.

14 (2) Repackage a drug previously dispensed to the patient at the
15 request of the patient or the patient's agent.

16 ~~SEC. 7.~~

17 *SEC. 6.* No reimbursement is required by this act pursuant to
18 Section 6 of Article XIII B of the California Constitution because
19 the only costs that may be incurred by a local agency or school
20 district will be incurred because this act creates a new crime or
21 infraction, eliminates a crime or infraction, or changes the
22 penalty for a crime or infraction, within the meaning of Section
23 17556 of the Government Code, or changes the definition of a
24 crime within the meaning of Section 6 of Article XIII B of the
25 California Constitution.